

**DOCKET NO.: TJU-2290**  
**PATENT APPLICATION**

**SERIAL NO.: 09/046,178**  
**FILED: MARCH 23, 1998**

**REMARKS**

Claims 2-24 are in the application.

Claims 2-24 have been rejected.

By way of this amendment, claims 2-8 have been canceled and the specification and claim 20 have been amended.

Upon entry of this amendment, claims 9-24 remain pending.

The specification has been amended to update the information in the section that refers to parent applications. No new matter has been added.

Claim 20 has been amended to correct an obvious error in dependency. No new matter has been added.

Claims 2-8 were rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 2-8 in related U.S. Patent No. 5,601,990.

By way of this amendment claims 2-8 have been canceled and the rejection is moot.

Claims 9-24 were rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-5 of related U.S. Patent No. 5,601,990 and claims 1-8 of related U.S. Patent No. 5,731,159.

Upon indication that claims 9-24 are otherwise patentable, Applicant will file a terminal disclaimer to obviate this rejection. Upon finding the claims otherwise patentable, Applicant respectfully invites the Examiner to contact Applicant's undersigned representative by telephone who will promptly transmit by telefax such a terminal disclaimer to facilitate allowance.

Claims 2-18 and 21-24 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 2-8 are asserted to be vague and indefinite because they are dependent on canceled claim 1.

Claims 21-24 are asserted to be confusing because it is not clear whether the negative control sample is a sample of normal colorectal tissue, a sample of normal tissue from another source or a sample known to contain no ST receptor protein.

Claims 2-8 have been canceled and the rejection is thereby moot as applied to those claims.

Applicant respectfully notes that, similar to claims 19 and 20, claim 23 does not refer to a negative control sample. Accordingly, the rejection as applied to claim 23 is inadvertent.

As applied to claims 9-18, 21, 22 and 24, Applicant respectfully requests reconsideration of the rejection under 35 U.S.C. §112, second paragraph. Applicant respectfully urges that those having ordinary skill in the art would immediately understand and appreciate the metes and bounds of claims 9-18, 21, 22 and 24.

Applicant respectfully urges that those having ordinary skill in the art know that a negative control assay is an assay designed to yield a negative result. When the assay is working correctly, the result of the negative control assay on a negative control sample is negative. Applicant respectfully urges that those having ordinary skill in the art would know what is meant by negative control assay and negative control sample in the context of the claims. Specifically, as used in the claims, a negative control assay is an assay intended to demonstrate the results seen in an individual who does not have metastasized colorectal cancer. Accordingly, those having ordinary skill in the art would know that the negative control samples referred to in the claims clearly refer to samples which would provide such results, i.e. samples which would produce results that are representative of the results that would be seen in a patient who does not have metastasized colorectal cancer. Thus, the term is not confusing.

Applicant respectfully urges that the specification clearly teaches that the claimed assays and kits are directed to detection of metastasized colorectal cancer using the expression of ST receptors as a marker to identify cells of colorectal origin. Accordingly, those skilled in the art would immediately understand that in methods and kits for identifying cells of colorectal

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origin in non-colorectal samples by detecting ST receptor expression, a negative control sample would **not** include normal or cancerous cells of colorectal origin but would include non-colorectal tissue samples or any other composition which would yield results distinguishable over the ST receptor expression of cells of colorectal origin. Applicant respectfully urges that those having ordinary skill in the art, reading the specification, would be able to design assays and kits as claimed which include negative control assays which include negative control samples that could be used to provide results that would allow patients with metastasized colorectal cancer to be identified.

Claims 9-18 and 21-24 are clear and definite and in compliance with the requirements of 35 U.S.C. §112, second paragraph. Applicant respectfully requests that the rejection of claims 9-18 and 21-24 under 35 U.S.C. §112, second paragraph, be withdrawn.

Claims 9-24 are in condition for allowance. Applicant respectfully requests that the Examiner indicate withdrawal of the rejection of claims 9-18 and 21-24 under 35 U.S.C. §112, second paragraph. Applicant's undersigned representative will promptly file a terminal disclaimer to obviate the obvious-type double patenting rejection and thereby allow the claims to advance to allowance.

Respectfully submitted,



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